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K133776

510(k) Summary
A-dec/W&H Electric Motor, Model EA-53

Date Summary Prepared: 01/14/2014

Submitter's Name and Address

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Contact Person

Bonnie Dundas
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Email: bonnie.dundas@a-dec.com

Device Name

Trade or Proprietary Name:	A-dec/W&H Electric Motor, Model EA-53
Common or Usual Name:	Dental Handpiece Electric Motor
Device Classification Name:	Controller, Foot, Handpiece and Cord
Regulation Number:	872.4200
Device Class:	I
Product Code:	EBW

Predicate Device

A-dec/W&H Electric Motor, Model EA-50LT (K032572)

Device Description

The A-dec/W&H Electric Motor, Model EA-53 is designed to accommodate existing and new Alegra, Proxeo, Endea, and Synea handpiece attachments for the purpose of performing dental restoration procedures. When equipped with the electric micromotor, the handpiece attachments provide the same effective drive force as would be provided by existing air motors. The significant advantage to driving a handpiece with the electric micromotor is the near-constant torque applied by the electric brushless micromotor. With air motor drive, the handpiece will tend to stall in extreme torque situations. The near-constant torque applied by the electric micromotor results in a more uniform and efficient dental reduction of the operatory site. The electric micromotor is autoclavable.

This system will be used in an integrated configuration on the dental operatory chair system. The motor controller is contained within the control head (dental unit) and acquires +24 VAC from the chair system 300W power supply secondary voltage output. The handpiece tubing extends from the control head to the ISO-E coupler. The micromotor is attached to the coupler on one end and attached on the other (output) end to a handpiece attachment suitable for the intended dental procedure. This system will include:

- Motor Controller
- Electric Micromotor
- Handpiece tubing with E-connector

Indications for Use

The A-dec/W&H Electric Motor kit is a device system comprised of a control unit that drives a DC electric micromotor that is activated by means of a footswitch. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis, and endodontic treatment, with use of a straight, right- angle, or contra-angle ISO E-type handpiece attachment of equal speed, gear-reduction speed, or gear-increasing speed.

Substantial Equivalence

The A-dec/W&H Electric Motor, Model EA-53 is substantially equivalent to the predicate device, the A-dec/W&H Electric Motor, Model EA-50LT in that it is a software driven dental control unit consisting of an AC motor and an integrated ISO coupler for connection to existing handpieces. As with the predicate device, it is integrated in a dental unit and uses the same water system and the same power supply. The software in the A-dec/W&H Electric Motor, Model EA-53 controls the following basic functions: motor on/off, motor direction, speed and torque regulation/limitation, led on/off, interaction with the control unit.

Changes from the predicate device EA-50LT (2003) to the new EA-53 (2013) are related to technological enhancements, such as a reduction in physical dimensional size, improved galvanic isolation, and improved user comfort due to lighter weight, improved lighting, and torque. The improved lighting for the A-dec/W&H EA-53 Electric Motor

system resulted from changing to an LED bulb from the traditional halogen bulb used in the EA-50LT predicate device. This new LED bulb provides a low heat, solid state light that consumes less power, thereby lasting longer, than a traditional halogen lamp. The changes do not impact the safety or efficacy of the device and the fundamental scientific technology of the device remains the same.

Non-Clinical Test Data

Torque, direction and stop time studies have been conducted to determine the parameters of the device functions. The A-dec/W&H Electric Motor, Model EA-53 has been successfully validated to confirm the performance of the device. The validation included testing of electromagnetic compatibility, electrical safety, thermal safety and photobiological safety, which have been conducted in accordance with applicable recognized consensus standards. Also sterilization and biocompatibility studies were done to determine the safety and effectiveness of the A-dec/W&H Electric Motor, Model EA-53.

Clinical Test Data

Clinical testing has not been conducted on these products.

Conclusions

Model EA-53 is deemed to be substantially equivalent to the predicate device, based upon similar technological/performance characteristics as compared to the predicate device and successful validation of the A-dec/W&H Electric Motor, Model EA-53.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

A-dec, Incorporated
Ms. Bonnie Dundas
Regulatory Audit Coordinator
2601 Crestview Drive
Newberg, OR 97132

Re: K133776
Trade/Device Name: A-dec/W&H Electric Motor, Model EA-53
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: May 1, 2014
Received: May 5, 2014

Dear Ms. Dundas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K133776

Device Name: A-dec/W&H Electric Motor EA-53

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription Use X And/Or Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Sheena A. Green -S
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